26. A pharmaceutical composition consisting essentially of about 600 micrograms/day of chromium as synthetic chromic tripicolinate and about 300 micrograms/day of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a greater than additive effect.

REMARKS

In response to the Office Action mailed November 2, 2001, Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments. Claims 1-26 are pending. Claims 11-26 were rejected and have been amended to comply with 37 C.F.R. §1.173(d). The specific changes to the amended claims are shown on a separate set of pages attached hereto and entitled **VERSTION WITH MARKINGS TO SHOW CHANGES MADE,** which follows the signature page of this Amendment. On this set of pages, the insertions are underlined. The amendments provided above are directed to matters of form only, and do not affect the scope of the claims. Accordingly, claims 11-26 are presented for examination.

Also submitted herewith is a Supplemental Reissue Declaration.

Payment of Fees

Upon filing this reissue application, Applicant inadvertently paid for only 5 independent claims. At the same time, attorneys for Applicant authorized the Commissioner to charge any additional fees to their Deposit Account. The Official Filing Receipt shows the correct number of independent claims, that being 7. The Patent and Trademark Office has not charged Applicant for the 2 additional independent claims. Applicant is submitting the fee for the 2 extra independent claims with this amendment and response as indicated on the transmittal claim fee calculations.

Broadening claims 11-23 were filed within the two year statutory period in conformance with 35 U.S.C. §251

Claims 11-23 were rejected under 35 U.S.C. §251 as being broadened in a reissue application allegedly filed outside the two year statutory period. The Examiner opines that "[s]ince the grandparent [sic - parent] issued more than 2 years prior to the instant application and since the limitations of the grandparent application overlaps the instant application, broadening is prohibited." Applicant respectfully disagrees.

When evaluating whether a reissue application is broader or narrow than the original application, one must look to the original patent. 35 U.S.C. §251. In the present case, the original patent (i.e. the patent to which the reissue is sought), is U.S. Patent No. 5,929,066. The original patent issued on July 27, 1999. The present reissue application was filed on July 24, 2001. Thus, the broadening reissue application was properly filed within two years of the grant of the original patent in conformance with 35 U.S.C. §251.

The PTO's apparent position is that because a priority parent application (U.S. Patent No. 5,789,401) issued more than 2 years prior to the instant application and because the limitations in the parent application "overlap" the instant application, broadening is prohibited. The Applicant notes, however, that it is the instant patent (i.e. U.S. Patent No. 5,929,066), which is the subject of the reissue application, not the patent issuing on the parent application. In fact, the issue date of the parent patent, for the purposes of evaluating the scope of the claims in this re-issue application, is irrelevant.

The burden is on the Examiner to make a *prima facie* case, under the statute, the regulations, and any controlling case law, to support the Section 251 rejection. No such *prima facie* case has been made. The Examiner has cited no authority whatsoever for the proposition that the two-year deadline for a broadening reissue runs from any patent other than the patent being reissued - in this case, U.S. Patent No. 5,929,066. The Examiner has not cited any support in the literal language of the statute. Indeed, the statutory language is clear, and is contrary to the position adopted in the office action. The Examiner has not cited any support in the regulations interpreting the statute. The Examiner has not cited any support in the MPEP, where the PTO's official interpretations of the statutes and rules are set forth. Nor has a single case been cited to support the proposition that the two year deadline for broadening reissue runs from anything other than the issue date of the patent being reissued. Nor can any such support be cited, because the rejection is legally incorrect. For all of these reasons, the PTO has failed to make a *prima facie* case under Section 251, and the rejection should be withdrawn.

Regarding failure to comply with 37 C.F.R. §1.173(d)

Claims 11-21 were objected to as failing to comply with 37 C.F.R. §1.173(d), which requires that any changes relative to the patent being reissued must be underlined. Claims 11-26 have been resubmitted in underlined form in compliance with 37 C.F.R. §1.173(d)(2) in an effort to obviate the Examiner's objection.

Regarding claims 24-26

Claims 24-26 were objected to in the Office Action Summary. However, the Examiner has made no reference to the objections in the text of the Office Action. In the interest of being thorough, we have resubmitted Claims 24-26 in underlined form to conform with 37 C.F.R. §1.173(d)(2).

Regarding the Supplemental Reissue Declaration

The reissue declaration, as originally filed, contains a typographical error, in that on page 2, lines 3-4, it refers to the addition of Claims 12-24, instead of 12-26 to correct defects in the original patent. This typographical error is corrected in the accompanying Supplemental Reissue Declaration

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, early issuance of a Notice of Allowance is solicited.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is invited to call the undersigned to discuss such issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 30 JAN 2002

By: _____

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Kindly amend claims 11-26 as follows:

11. A method for reducing hyperglycemia or stabilizing the level of serum glucose comprising administering to an individual in need thereof between about 50 and 1,000 micrograms per day of chromium as synthetic chromic tripicolinate in combination with between about 25 μg and 200 mg per day of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a greater than additive effect.

12. A method for reducing hyperglycemia or stabilizing the level of serum glucose comprising administering to an individual in need thereof a composition consisting essentially of between about 50 and 1,000 micrograms per day of chromium as synthetic chromic tripicolinate in combination with between about 25 micrograms and 200 milligrams per day of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a greater than additive effect.

13. The method of claim 12, wherein the individual is a human.

14. The method of claim 12, comprising administering between about 500 and 1,000 micrograms per day of chromium as synthetic chromic tripicolinate.

15. The method of claim 12, comprising administering between about 1 milligram and 100 milligrams biotin per day.

16. The method of claim 12, comprising administering about 600 micrograms of chromium as synthetic chromic tripicolinate and about 300 micrograms of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a greater than additive effect.

17. The method of claim 12, comprising administering about 400 micrograms of chromium as synthetic chromic tripicolinate and about 200 micrograms of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a greater than additive effect.

18. The method of claim 12, wherein said chromic tripicolinate is in a pharmaceutically acceptable carrier.

19. The method of claim 12, wherein said biotin is in a pharmaceutically acceptable carrier.

20. The method of claim 12, wherein said chromic tripicolinate is orally administered.

21. The method of claim 12, wherein said biotin is orally administered.

22. The method of claim 12, wherein said chromic tripicolinate is parenterally administered.

23. The method of claim 12, wherein said biotin is parenterally administered.

24. A pharmaceutical composition consisting essentially of chromium as synthetic chromic tripicolinate and biotin, wherein the ratio of chromium to biotin is between about 2:1 and 1:200 (w/w), wherein the amounts of chromic tripicolinate and biotin are selected together to provide a greater than additive effect.

25. A pharmaceutical composition comprising about 600 micrograms/day of chromium as synthetic chromic tripicolinate and about 300 micrograms/day of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a greater than additive effect.

26. A pharmaceutical composition consisting essentially of about 600 micrograms/day of chromium as synthetic chromic tripicolinate and about 300 micrograms/day of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a greater than additive effect.

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